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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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HM12/0427

EXAMINER

VANDER VEGT, F

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

04/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/310,885

Applicant(s)
Lamb et al

Examiner
F. Pierre VanderVegt

Art Unit
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Apr 17, 2001

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-25 and 27-32 ~~is/are~~ are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-25 and 27-32 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) ☐ Other:

DETAILED ACTION

This application is a continuation-in-part of application serial number PCT/GB97/03058.

Claim 26 has been canceled.

Claims 1-25 and 27-32 are currently pending in this application.

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1. In view of miscommunication regarding the claimed inventions of the application in the prior Restriction Requirement mailed October 3, 2000 and the resultant errors in the subsequent Office Action mailed January 16, 2001, as a courtesy to Applicants the prior actions are hereby vacated and are replaced in total by this restriction requirement.

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Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

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Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6 and 27-32, drawn to a method of immunotherapy using a notch ligand, classified in class 514, subclass 2.
- II. Claims 7-12, drawn to a method of tolerizing T cells to an antigen or allergen using *Notch*-ligand expressing antigen presenting cells (APCs), classified in class 435, subclass 373.

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III. Claims 13-18, drawn to notch ligand conjugates and a kit comprising *Notch* protein or family members, classified in class 530, subclass 350 and class 435, subclass 810.

5 IV. Claim 19, drawn to an assay determining the effect of a compound on ligand binding to *Notch*, classified in class 436, subclass 501.

V. Claim 20, drawn to a *Delta* or *Serrate* ligand, classified in class 530, subclass 350.

10 VI. Claim 21, drawn to an assay for free *Serrate*, *Notch* or *Delta* family members in vivo, classified in class 424, subclass 9.1.

VII. Claim 22, drawn to an assay for determining a compound's effect on *Notch* or ligand expression, classified in class 435, subclass 6.

15 VIII. Claim 23, drawn to compounds which affect *Notch* or ligand expression, classified in class 536, subclass 24.5.

20 IX. Claims 24 and 25, drawn to a compound which down regulates *Delta* or *Serrate* expression, classified in class 536, subclass 24.5.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different
25 functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method of in vivo therapy in Group I and a method of in vitro tolerization of immune cells in Group II. The method of Group I involves the direct administration of a therapeutic substance to an individual while Group II is drawn to the sensitization of cells with said substance in culture.

30 Inventions III, V, VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to compounds which are distinct from one another.

35 Inventions IV, VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the

different inventions are materially different assays using different test reagents and are designed to provide different end results, i.e., looking for different products.

4. Because these inventions are distinct for the reasons given above and have acquired a
5 separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

10 In Group I -

a) allergy

b) autoimmunity

c) graft rejection

d) tumor induced aberrations

15 e) infectious disease.

The species are distinct, one from another, because each type of condition requires response from different subsets of immune cells which require different suppression or activation for treatment of the condition.

Should Applicant elect Group I, Applicant is further required under 35 U.S.C. 121 to elect
20 a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-3, 5, 6, 27 and 29-32 are generic in Group I.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon,
25 including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, Applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. A telephone call was made to, and a message regarding restriction requirement left on the voice mail of, Thomas Kowalski on April 24, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

8. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Tuesday through Friday and odd-numbered Mondays (on year 2001 365-day calendar) from 6:30 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful,

the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

5 F. Pierre VanderVegt, Ph.D.
Patent Examiner
Technology Center 1600
April 26, 2001



**F. PIERRE VANDERVEGT
PATENT EXAMINER**